

§ 112.6

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(4) Name of licensee or subsidiary appearing on the label as the producer.

(h) At the time of an inspection, or when requested by APHIS, licensees or permittees shall make all labels and master labels, including labels approved for use but exempted from filing under the master label system, available for review by authorized inspectors. Such labels shall be identical to the approved label or master label except for physical dimensions, reference to recoverable volume or doses and/or certain minor differences permitted in accordance with paragraph (d) of this section.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 12094, May 9, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 49 FR 21044, May 18, 1984; 56 FR 66783, Dec. 26, 1991; 59 FR 43445, Aug. 24, 1994; 61 FR 29464, June 11, 1996; 61 FR 33175, June 26, 1996; 64 FR 43044, Aug. 9, 1999; 75 FR 20772, Apr. 21, 2010; 80 FR 39675, July 10, 2015]

§ 112.6 Packaging biological products.

(a) Each multiple-dose final container of a biological product which requires a diluent for administration shall be packaged in an individual carton with a container of the proper volume of diluent for that dose as specified in the filed Outline of Production. Each multiple-dose final container of a product which does not require a diluent for administration need not be packaged in an individual carton unless the final container labeling does not contain all information required by the regulations. Such information must be included in or on a carton. Exceptions are provided in paragraphs (c) and (d) of this section and § 112.8.

(b) Single-dose final containers of a product need not be packaged one per carton. For single-dose products which require a diluent for administration, the number of containers of the proper amount of diluent specified in the filed Outline of Production for the number of doses contained in the carton shall be included in each carton.

(c) Poultry products for mass administration (including but not limited to administration through drinking water and spray) and products used in automatic vaccinating systems (including but not limited to pneumatic beak

injectors and automated needle injectors) may be packaged in multiple-dose final containers as specified in the filed Outline of Production. Poultry products for manual administration to individual birds shall not exceed 1,000 doses in each final container. Diluent need not be packaged with the final container(s) of the product, but the licensee shall provide the required number of containers of diluent as specified in the filed Outline of Production. The following requirements apply to cartons containing more than one final container of poultry product:

(1) They shall be sealed prior to leaving the licensed establishment.

(2) The contents may not be repackaged.

(3) The contents of such cartons may not be sold in fractional units.

(4) The following statement must appear in a prominent place on the carton label: "Federal regulations prohibit the repackaging or sale of the contents of this carton in fractional units. Do not accept if seal is broken."

(d) Diluent for the following products need not be packaged with the final container(s) of the product, but the licensee shall provide the consumer with the required number of containers of the proper amount of diluent as specified in the filed Outline of Production:

(1) Marek's Disease Vaccine.

(2) Poultry vaccines administered to individual birds using automatic vaccinating equipment.

(e) Final containers of biological product prepared at a licensed establishment, or imported, in cartons or other containers shall not be removed from such cartons or containers for sale or distribution, unless each final container bears, or is packaged in a carton with, complete and approved labeling which is affixed to or included with each container by the licensed establishment producing the product or by the producer in the case of imported product: *Provided*, That this paragraph is not intended to apply to licensed veterinary practitioners administering or dispensing biological products in the course of their practice under a veterinary-client-patient-relationship as that term is used in § 107.1.

(f) Labels which are affixed to or included with a biological product shall

not be removed or altered in any manner.

[47 FR 8761, Mar. 2, 1982, as amended at 48 FR 12691, Mar. 28, 1983; 59 FR 43445, Aug. 24, 1994; 64 FR 43044, Aug. 9, 1999]

§ 112.7 Special additional requirements.

The label requirements in this section are additional to those prescribed elsewhere in this part.

(a) In the case of biological products containing live Newcastle Disease virus, a caution statement indicating that Newcastle Disease can cause inflammation of the eyelids of humans, and a warning to the user to avoid infecting his eyes shall be included on the enclosure.

(b) In the case of a biological product containing infectious bronchitis virus, all labels shall show the infectious bronchitis virus type or types used in the product. Abbreviation is permitted.

(c) In the case of a biological product containing inactivated rabies virus, carton labels, enclosures, and all but very small final container labels shall include a warning against freezing and the recommendations provided in this paragraph.

(1) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(2) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.209, paragraph (b) or (c), or both.

(d) In the case of a biological product containing modified live rabies virus, the carton labels, enclosures, and all but very small final container labels shall include the recommendations provided in this paragraph.

(1) For low egg-passage (below the 180th egg-passage level) the statement "For Use in Dogs Only! Not For Use in Any Other Animal!"

(2) For other vaccines containing modified live rabies virus, the statement "For Use In (designate animal(s)) Only! Not For Use In Any Other Animal!"

(3) Intramuscular injection at one site in the thigh shall be recommended.

(4) The statement "In event of accidental exposure to the vaccine virus, the possible hazard to human health

should be considered and State Public Health Officials should be consulted for specific recommendations" shall be prominently placed on all carton labels and on enclosures, if used.

(5) That vaccine be administered to animals at 3 months of age or older, with a repeat dose 1 year later.

(6) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.312, paragraph (b) or (c), or both.

(e) In the case of bovine rhinotracheitis vaccine containing modified live virus, all labeling except small final container labels shall bear the following statement: "Do not use in pregnant cows or in calves nursing pregnant cows." *Provided*, That such vaccines which have been shown to be safe for use in pregnant cows may be excepted from this label requirement by the Administrator.

(f) Unless otherwise authorized in a filed Outline of Production, labels for inactivated bacterial products shall contain an unqualified recommendation for a repeat dose to accomplish primary immunization to be given at an appropriate time interval: *Provided*, That, repeat dose recommendations prescribed in paragraphs (f)(1) through (3) of this section are required for products containing the fractions listed.

(1) *Clostridium haemolyticum*. "Repeat the dose every 5 or 6 months in animals subject to reexposure."

(2) *Erysipelothrix rhusiopathiae*. "Swine: For breeding animals, repeat after 21 days and annually. Turkeys: Repeat dose every 3 months."

(3) *Clostridium botulinum Type C*. "Revaccinate breeders 1 month before breeding."

(g) In the case of a liquid product authorized in a filed Outline of Production to be used as a diluent in a combination package, the carton labels and enclosures used for serials which are either not tested for bactericidal or viricidal activity or have been found unsatisfactory by such test shall contain the statement: "CAUTION: DO NOT USE AS DILUENT FOR LIVE VACCINES."

(h) In the case of wart vaccine, recommendations shall be limited to use in cattle. Indications for use shall be